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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

JONES, D

ART UNIT	PAPER NUMBER
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1619

DATE MAILED:

08/28/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/405046

Applicant(s)

meade et al

Examiner

P. Jones

Group Art Unit

1619

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 1/3/00, 6/24/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application.
- Of the above claim(s) 2-5, 8-11 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 6, 7, 12-19 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 (sheet) ☐ Interview Summary, PTO-413
- ☒ Notice of References Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

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### ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 7, filed 6/26/00, wherein (1) Applicant elected to prosecute the species as set forth in the response; and (2) claims 12-19 were added.

Note: Claims 1-19 are pending.

### APPLICANT'S INVENTION

2. Applicant's invention is directed to magnetic resonance imaging agents as set forth in independent claims 1- 8.

### COMMENTS ON APPLICANT'S ELECTED SPECIES

3. Claims 1, 6, 7, 12, 16, and 17 read on Applicant's elected species. Claim 2 as indicated in Applicant's response does not read on the elected species because R1-R12 cannot equal CH<sub>2</sub>CO-peptide and at least one of X1-X4 and R1-R12 is not a blocking moiety.

Note regarding priority of elected species: The species Applicant has elected for examination purposes contains new matter. Thus, Applicant is not <sup>afforded</sup> ~~afford~~ the priority date of the parent applications.

### WITHDRAWN CLAIMS

4. Claims 2-5, 8-11, 13-15, 18, and 19 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

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Note: While claims 13-15, 18, and 19 were not examined on the basis of whether or not they read on the prior art, the claims were examined for new matter.

### STATUTORY DOUBLE PATENTING

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5,980,862. This is a double patenting rejection.

7. Claims 6 and 7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 6 of prior U.S. Patent No. 5,707,605. This is a double patenting rejection.

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## **OBVIOUSNESS-TYPE DOUBLE PATENTING**

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,980,862. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 6 of the instant invention is directed to a mri agent wherein the blocking moiety is attached to a chelator which binds in at least a first coordination site of the metal and the patented invention

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discloses that the chelator has coordination atoms in at least 5 coordination sites. Thus, the instant invention encompasses the patented invention.

10. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 7 of U.S. Patent No. 5,707,605. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented invention is directed to a mri agent wherein the blocking moiety is attached to a chelator which binds in at least a first coordination site of the metal and the claims of the instant invention discloses that the chelator has coordination atoms in at least 5 coordination sites. Thus, the patented invention is encompassed in the instant invention.

#### **NEW MATTER REJECTION**

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 12-19 contain new matter. In particular, the specification does not disclose an mri agent wherein R26-peptide or CO-peptide is attached to a modified DOTA structure. While it is noted that Applicant states that the claims do not contain new matter on the basis that they were broadly disclosed in the specification, the specification does not disclosed the structures now being claimed by Applicant. If Applicant is in disagreement with the Examiner, it is respectfully requested that the specific page and line be disclosed wherein the structures are disclosed.

### 103 REJECTION

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 6, 7, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margerum et al (WO 95/28966).

**Margerum et al** disclose dendrimeric compounds that may be linked to a plurality of diagnostically or therapeutically active moieties (abstract). In particular, in Example 7 (pages 74-76), Margerum et al disclose the preparation of an oligolysine comprising oligomeric lysine units that generate a small branched homo-lysine peptide. The chelant-oligolysine structure disclosed on page 75 contains the core structure being claimed by Applicant in addition to the attachment of

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tBu at three of the COO- positions and a NH-group to the C=O position. The reference discloses various methods of obtaining the chelate-oligolysine units: (1) the tBu groups of the modified DOTA structure are removed and Gd incorporated into the molecule using standard techniques known in the art (page 75, third paragraph). (2) Oligomerization of the chelate-lysine monomer unit is achieved by solid phase peptide synthesis to yield a metal chelate oligolysine unit (page 75, fourth paragraph). (3) The modified DOTA structure may be that disclosed on page 76, line 3, wherein X in the presence of a base yields the desired chelate-oligolysine unit which is isolated after acidic cleavage from the solid support (such process may be followed by incorporation of GD to give the metal-chelated oligolysine compound). While Margerum et al does not specifically disclose that the mri agent hinders the rapid exchange of water in the remaining coordination sites, it would be obvious to one of ordinary skill in the art that the structure of Margerum et al hinders rapid water exchange because (a) both Margerum et al and Applicant disclose a modified DOTA structure attached to a peptide; and (b) a skilled practitioner in the art would expect that the qualities possessed by the species of Applicant's invention would be the same qualities possessed by the modified DOTA-peptide containing species of Margerum.

## **SPECIFICATION**

15. The disclosure is objected to because of the following informalities: (1) on page 25, lines 24-29, the structure is surrounded by text. Thus, it is unclear whether Applicant intended the structure to be on a separate line. (2) Page 36 of the specification is a blank sheet of paper. (3)



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On page 1, lines 8-9, Applicant disclose that priority of a PCT application is being claimed. However, the PCT data is not listed under the continuing data section of the filewrapper even though all other Applicant's appearing in the first paragraph of the specification are disclosed. Thus, it is suggested that 'priority...1996' be deleted.

Appropriate correction is required.

#### COMMENTS/NOTES

16. Applicant is reminded that the recitation that an element is 'capable of' performing a function is not a positive limitation but only requires the ability to so perform that function. Thus, it does not constitute a limitation in any patentable sense (*In re Hutchison*, 69 USPQ 138).

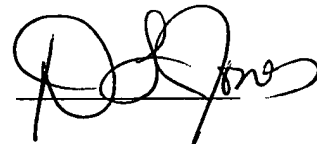
17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to the Group 1600 fax machine at (703) 308-4556. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30; November 15, 1989.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. Examiner Jones can generally be reached from Monday through Friday between 7:00 a.m. and 3:30 p.m. If the

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Examiner cannot be reached, questions may be addressed to her supervisor, Diana Dudash, whose phone number is (703) 308-2328.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'D. L. Jones', written over a horizontal line.

D. L. Jones  
Patent Examiner  
Art Unit, 1619

August 22, 2000